

Wednesday, May 06, 2009

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Meeting Minutes:

- DailyMed Product Identification system
 - <http://dailymed.nlm.nih.gov/dailymed/prdsearch.cfm>.
- SPL Validator
 - The [FDA Data Standards Council's website's home page](#) to include a new page titled Validators. On this new web page is a link to a validation tool, [Pragmatic Validator Lite™](#), that can be utilized to validate SPL Release Four documents prepared for submission to FDA.
 - SPL r4 validators <http://www.fda.gov/oc/datacouncil/validate.html>
- FDA Data standards updates
 - new doctypes & marketing categories, updated terminology files, postal code validation
 - Additional document type: "Medical Device" - (<http://www.fda.gov/oc/datacouncil/term.html#content>)
 - Terminology page update - 4 new marketing categories: (<http://www.fda.gov/oc/datacouncil/term.html#marcat><http://internet-dev.fda.gov/oc/datacouncil/term.html>)
 - Updated to include updated XML terminology files for document types, UNII's, marketing categories - (http://www.fda.gov/oc/datacouncil/terminology_lists.zip)
 - UNII list with synonyms <http://www.fda.gov/oc/datacouncil/UNIIs.zip>
 - Updated to include updated XML file for postal code validation (http://www.fda.gov/oc/datacouncil/additional_validation_only_lists.zip)
- SPL r4 submissions to date - status check, discussion of experiences
 - Getting different responses on what to do when there isn't a UNII code - if a UNII for an inactive ingredient is not available, you can remove the inactive ingredient from the list.
 - One company has submitted several labels – two have appeared on DailyMed already.
 - Another company has submitted a drug listing and gotten comments back from SPL group
 - Concerns about third-party suppliers – is there an incentive for them to file sooner than end of year?
 - Getting set up on the Gateway – check the resource site: <http://www.fda.gov/esg/default.htm>. Lots of great feedback about the ESG staff!
 - Some organizations are sending in drug listings proactively; others are planning to send only when there is a listing change. Some are considering submitting on an Annual Report schedule and/or when there's a labeling change.

Subteam Updates

Medical Devices Subteam

- Meeting scheduled for May 21 at 10:00. Overview of activities at HL7. Participation by Terrie Reed and Jay Crowley (CDRH).
- The group is fairly small. Anyone interested in joining/re-joining the Medical Device subteam, please contact Myron Finseth @ myron.finseth@medtronic.com.

Generics Subteam

- Some discussion about what software was being used.

ER/DL Subteam

- Mass de-listing of products for double-listed products (products manufactured outside of the United States)
- Still an open issue: Export-only products – ongoing topic with lots of discussions. Some issues – do these need to have NDC codes? Foreign languages may be an issue for many software vendors.
- Open question about how ‘deep’ to list the manufacturers
- Additional issues? Raise them with this team – contact Michael.fahmy@bms.com.

No additional updates from Biologics Subteam, OTC Subteam, Veterinary Medicine Subteam

Next meeting scheduled for Wednesday, May 18, 2009 from 1 – 2:30.

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